DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
94728d
Central Region

Food and Drug Administrat
Waterview Corporate Cent
10 Waterview Blvd., 3rd Fl
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 19, 2004

File # 04 -NWJ-13

Randall Copeland
Executive Vice-president of Operations
Menu Foods, Inc.
9130 Griffith Morgan Lane
Pennsauken, NJ 08110

Dear Mr. Copeland:

We conducted an inspection of your animal feed manufacturing operation, located at 9130 Griffith Morgan Lane, Pennsauken, New Jersey, on February 2 and 3, 2004. This inspection revealed a significant deviation from the requirements set forth in Title 21, Code of Federal Regulations Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

During this inspection our investigators determined that you manufactured [redacted] a canned animal food, [redacted] This product contains protein sources of bovine origin including beef lung. However, this lot failed to bear the cautionary statement "Do Not Feed to Cattle or Other Ruminants," as required by 21 CFR 589.2000(d)(1) and (c)(1)(i). FDA further suggests that this statement be distinguished by different type size or color, or other means of highlighting so that the statement is readily noticed by the purchaser. You introduced this product without the required cautionary statement into interstate commerce on October 22, 2003.

Under 21 CFR 589.2000(g)(2), such a deviation causes products being distributed by your facility to be deemed misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and these products may not be lawfully introduced, or delivered for introduction, into interstate commerce. This labeling deviation was previously brought to your attention during our inspection of September 29 & 30, 2003.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. Your response should include an explanation of each step being taken to correct the violation, and prevent a reoccurrence. You may wish to include in your response documentation concerning procedures you have implemented or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above. If you have questions regarding any issue in this letter, please contact Mr. Manney directly.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District